



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

1 July 2014
EMA/HMPC/55843/2011
Committee on Herbal Medicinal Products (HMPC)

Community herbal monograph on *Matricaria recutita* L., flos

Draft

Discussion in Working Party on Community monographs and Community list (MLWP)	January 2011 September 2011 November 2011 September 2013 November 2013 January 2014 March 2014
Adoption by Committee on Herbal Medicinal Products (HMPC) for release for consultation	1 July 2014
End of consultation (deadline for comments). Comments should be provided using this template to hmpc.secretariat@ema.europa.eu	31 October 2014
Rediscussion in Working Party on Community monographs and Community list (MLWP)	
Adoption by Committee on Herbal Medicinal Products (HMPC)	

Keywords	Herbal medicinal products; HMPC; Community herbal monographs; traditional use; <i>Matricaria recutita</i> L., flos; Matricariae flos; Matricaria flower
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Community herbal monograph on *Matricaria recutita* L., flos

1. Name of the medicinal product

To be specified for the individual finished product.

2. Qualitative and quantitative composition^{1,2}

Well-established use	Traditional use
	<p>With regard to the registration application of Article 16d(1) of Directive 2001/83/EC as amended</p> <p><i>Matricaria recutita</i> L., flos (matricaria flower)</p> <p>i) Herbal substance</p> <p>As defined in the Ph. Eur. monograph.</p> <p>ii) Herbal preparations</p> <p>a) Comminuted herbal substance</p> <p>b) Liquid extract (1:1), extraction solvent ethanol 96% V/V : water : ammonia solution 10% V/V (50:47.5:2.5)³</p> <p>c) Liquid Extract (1:4.3-5.7), extraction solvent ethanol 96% V/V : water : ammonia solution 10% V/V (50:47.5:2.5)</p> <p>d) Liquid extract (1:1), extraction solvent ethanol 48% V/V : ammonia solution 10% m/m (39:1)</p> <p>e) Liquid extract (1:1), extraction solvent ethanol 45% V/V : ammonia solution 10% (14.7:1)</p> <p>f) Dry extract (4-7:1), extraction solvent ethanol 50% m/m</p> <p>g) Liquid extract (1:1.7-2.6), extraction solvent ethanol 48% V/V</p> <p>h) Liquid extract (1:1), extraction solvent ethanol 55% V/V</p> <p>i) Liquid extract (0.5:1), extraction solvent ethanol 96% V/V</p> <p>j) Liquid extract (2:1), extraction solvent ethanol 70% V/V</p>

¹The declaration of the active substance(s) for an individual finished product should be in accordance with relevant herbal quality guidance.

² The material complies with the Ph. Eur. monograph (ref. 01/2008: 0404).

³ The material complies with the Ph. Eur. monograph (ref. 01/2008: 1544).

Well-established use	Traditional use
	k) Liquid extract (1:4.1-4.6), extraction solvent ethanol 55% V/V : Poloxamer 188 (993:3) l) Liquid extract (1:1.8-2.1), extraction solvent ethanol 52% V/V : macrogol hydroxystearate (99.5:0.5) m) Liquid extract (1:4.0-4.5) extraction solvent ethanol 38.5% m/m (containing 1.36% sodium acetate trihydrate, 0.45% sodium ascorbate and 0.41% sodium hydroxide) n) Liquid extract (2.7-5.5:1), extraction solvent ethanol 95.4% V/V (containing 0.22% sodium acetate, 0.12% sodium hydroxide) o) Dry extract (11-16:1), extraction solvent ethanol 95.4% V/V (containing 0.22% sodium acetate, 0.12% sodium hydroxide) p) Liquid extract (1:2.0-2.8), extraction solvent propan-2-ol 48% V/V

3. Pharmaceutical form

Well-established use	Traditional use
	<p>Herbal substance or comminuted herbal substance as herbal tea for oral use and inhalation.</p> <p>Herbal preparations in liquid dosage forms for oral use.</p> <p>Herbal substance or comminuted herbal substance for infusion preparation for oromucosal use or cutaneous use.</p> <p>Herbal preparations in liquid dosage forms for preparation of dilutions for steam inhalation.</p> <p>Herbal preparations in semi-solid dosage forms for cutaneous use.</p> <p>Herbal preparations in liquid dosage forms for use as bath additives.</p> <p>The pharmaceutical form should be described by the European Pharmacopoeia full standard term.</p>

4. Clinical particulars

4.1. Therapeutic indications

Well-established use	Traditional use
	<p>Indication 1)</p> <p>Traditional herbal medicinal product used for the symptomatic treatment of minor gastro-intestinal</p>

Well-established use	Traditional use
	<p>complaints such as bloating and minor spasms.</p> <p>Indication 2)</p> <p>Traditional herbal medicinal product used for the relief of symptoms of common cold.</p> <p>Indication 3)</p> <p>Traditional herbal medicinal product for the treatment of minor ulcers and inflammations of the mouth and throat.</p> <p>Indication 4)</p> <p>Traditional herbal medicinal product used for adjuvant therapy of irritations of skin and mucosae in the anal and genital region, after serious conditions have been excluded by a medical doctor.</p> <p>Indication 5)</p> <p>Traditional herbal medicinal product used for the treatment of minor inflammation of the skin (sunburn) and superficial wounds and small boils (furuncles).</p> <p>The product is a traditional herbal medicinal product for use in specified indications exclusively based upon long-standing use.</p>

4.2. Posology and method of administration⁴

Well-established use	Traditional use
	<p>Preparation a)</p> <p>Indication 1)</p> <p><i>Adolescents, adults and elderly</i></p> <p>Single dose: 1.5-4 g of the comminuted herbal substance in 150 ml of boiling water as a herbal infusion</p> <p>Daily dose: 3-4 times</p> <p><i>Children (6 months - 2 years)</i></p> <p>Single dose: 0.5-1.0 g</p> <p>Daily dose: 2-4 times</p> <p><i>Children (2-6 years)</i></p> <p>Single dose: 1.0-1.5 g</p> <p>Daily dose: 2-4 times</p>

⁴ For guidance on herbal substance/herbal preparation administered as herbal tea or as infusion/decoction/macerate preparation, please refer to the HMPC 'Glossary on herbal teas' (EMA/HMPC/5829/2010 Rev.1).

Well-established use	Traditional use
	<p><i>Children (6-12 years)</i> Single dose: 1.5-3.0 g Daily dose: 2-4 times</p> <p>Indication 2)</p> <p><i>Adolescents, adults and elderly</i> Single dose: 3-10 g of comminuted herbal substance in 100 ml water</p> <p>Indication 3)</p> <p><i>Children (6-12 years), adolescents, adults and elderly</i> Single dose: Comminuted herbal substance for infusion preparation for oromucosal use: 1-5 g in 100 ml water, for rinsing and gargling Daily dose: several times</p> <p>Indication 4)</p> <p><i>Adolescents, adults and elderly</i> Single dose: 4.5-5 g comminuted herbal substance per 1 l for irrigation Daily dose: several times</p> <p>Indication 5)</p> <p><i>Adolescents, adults and elderly</i> Single dose: 2.4-4 g/150 ml water Daily dose: several times For washings and impregnated dressings</p> <p>Preparation b)</p> <p>Indication 1)</p> <p><i>Adolescents, adults and elderly</i> Single dose: 10 ml in 150 ml warm water Daily dose: 3-4 times</p> <p>Preparation c)</p> <p>Indication 3) (for gargling or rinsing) and Indication 5) (for washing or impregnated dressings with infusions)</p> <p><i>Adolescents, adults and elderly</i> Single dose: 10 ml in 150 ml warm water Daily dose: 3-4 times</p> <p>Preparation d)</p> <p>Indication 1)</p> <p><i>Adolescents, adults and elderly</i> Single dose: 3 ml in 150 ml water Daily dose: 3-4 times</p>

Well-established use	Traditional use
	<p>Indication 2)</p> <p><i>Adolescents, adults and elderly</i></p> <p>Single dose: 1.5 ml in 150 ml water for inhalation</p> <p>Daily dose: 1-2 times</p> <p>Indication 3)</p> <p><i>Adolescents, adults and elderly</i></p> <p>Single dose: 1.5 ml in 150 ml water</p> <p>Daily dose: several times</p> <p>Indication 4)</p> <p><i>Adolescents, adults and elderly</i></p> <p>Single dose: 1.5 ml in 150 ml water for irrigations</p> <p>Single dose: 5 ml per 1 l water for partial bathes</p> <p>Daily dose: several times</p> <p>Indication 5)</p> <p><i>Adolescents, adults and elderly</i></p> <p>Single dose: 1.5 ml in 150 ml water</p> <p>Daily dose: several times</p> <p>Preparation e)</p> <p>Indication 1)</p> <p><i>Adolescents, adults and elderly</i></p> <p>Single dose: 5 ml in 150 ml water</p> <p>Daily dose: up to 4 times</p> <p><i>Children (6-12 years)</i></p> <p>Single dose: 2.5 ml in 150 ml water</p> <p>Daily dose: up to 4 times</p> <p>Indication 2)</p> <p><i>Adolescents, adults and elderly</i></p> <p>Single dose: 5 ml in 150 ml for inhalation</p> <p>Daily dose: several times</p> <p>Indication 3)</p> <p><i>Adolescents, adults and elderly</i></p> <p>Single dose: 2.5 ml in 125 ml water</p> <p>Daily dose: 3-4 times</p> <p>Indication 4)</p> <p><i>Adolescents, adults and elderly</i></p> <p>Single dose: 20 ml per 1 l water for compresses and irrigation</p> <p>Single dose: 10 ml per 1 l water for partial bathes</p> <p>Daily dose: several times</p>

Well-established use	Traditional use
	<p>Indication 5)</p> <p><i>Adolescents, adults and elderly</i></p> <p>Single dose: 20 ml per 1 l water for compresses and irrigation</p> <p>Single dose: 10 ml per 1 l water for partial bathes</p> <p>Daily dose: several times</p> <p>Preparation f)</p> <p>Indication 5) (sun burn)</p> <p><i>Adolescents, adults and elderly</i></p> <p>Single dose: Apply few drops in a thin layer on the affected area.</p> <p>Daily dose: several times</p> <p>Preparation g)</p> <p>Indication 1)</p> <p><i>Adolescents, adults and elderly</i></p> <p>Single dose 1.5 ml in 150 ml water</p> <p>Daily dose: 3-4 times</p> <p><i>Children (6-12 years)</i></p> <p>Single dose: 0.7–1 ml in 150 ml water</p> <p>Daily dose: 3-4 times</p> <p>Indication 2)</p> <p><i>Adolescents, adults and elderly</i></p> <p>Single dose: 15 ml per 1 l hot water for steam inhalation</p> <p>Daily dose: 1-2 times</p> <p>Indication 4) and 5)</p> <p><i>Adolescents, adults and elderly</i></p> <p>Single dose: 15 ml per 1 l hot water for compresses and irrigation or partial bathes</p> <p>Daily dose: several times</p> <p>Preparation h)</p> <p>Indication 1) and 3)</p> <p><i>Adolescents, adults and elderly</i></p> <p>Single dose: 1-2 ml in 150 ml warm water for oral use and mouth rinsing or gargling</p> <p>Daily dose: up to 4 times</p> <p><i>Children (6-12 years)</i></p> <p>Single dose: 0.5-1 ml in 150 ml warm water</p> <p>Daily dose: up to 4 times</p>

Well-established use	Traditional use
	<p>Indication 2) <i>Adolescents, adults and elderly</i> Single dose: 15 ml per 1 l hot water for steam inhalation Daily dose: 1-3 times</p> <p><i>Children (6-12 years)</i> Single dose: 0.5-1 ml in 150 ml warm water for steam inhalation Daily dose: up to 4 times</p> <p>Indication 4) <i>Adolescents, adults and elderly</i> Single dose 15 ml per 1 l water for compresses and irrigation Single dose: 15-30 ml per 5 l water for partial bathes Daily dose: one to several times</p> <p>Preparation i)</p> <p>Indication 1) and 3) <i>Adolescents, adults and elderly</i> Single dose: 5 ml in 150 ml water Daily dose: 3-4 times</p> <p>Indication 5) <i>Adolescents, adults and elderly</i> Single dose: 10 ml plus 90 ml hot water Daily dose: several times</p> <p>Preparation j)</p> <p>Indication 1) and 3) <i>Adolescents, adults and elderly</i> Single dose: 2.5-5 ml in 50-100 ml water Daily dose: 3 times</p> <p>Indication 5) <i>Adolescents, adults and elderly</i> Single dose: 5-10 ml in 100 ml water for washings and compresses Daily dose: 3 times</p> <p>Preparation k)</p> <p>Indication 1) <i>Adolescents, adults and elderly</i> Single dose: 5 ml in 150 ml warm water Daily dose: 3-4 times</p>

Well-established use	Traditional use
	<p>Indication 2)</p> <p>Adolescents, adults, elderly: Single dose: 40 ml per 1 l hot water Daily dose: 1-2 times</p> <p>Indication 3)</p> <p><i>Adolescents, adults and elderly</i> Single dose: 5 ml in 100 ml water Daily dose: 3 times</p> <p>Indication 4)</p> <p><i>Adolescents, adults and elderly</i> Single dose: 20 ml per 1 l water for hip baths Single dose: 40 ml per 1 l water for washings and impregnated dressings Daily dose: one to several times</p> <p>Indication 5)</p> <p><i>Adolescents, adults and elderly</i> Single dose: 40 ml per 1 l water Daily dose: one to several times</p> <p>Preparation I)</p> <p>Indication 1)</p> <p><i>Adolescents, adults and elderly</i> Single dose: 1 g in 150 ml water Daily dose: up to 4 times</p> <p><i>Children (6-12 years)</i> Single dose: 0.7 g in 150 ml water Daily dose: up to 4 times</p> <p>Indication 2)</p> <p><i>Adolescents, adults and elderly</i> Single dose: 10-20 ml per 1 l water Daily dose: one to several times</p> <p>Indication 3)</p> <p><i>Adolescents, adults and elderly</i> Single dose: 0.7-1.0 ml in 75 ml water Daily dose: one to several times</p> <p>Indication 4)</p> <p><i>Adolescents, adults and elderly</i> Single dose: 7.5-15 ml per 1 l water for hip bathes and irrigations Daily dose: one to several times daily Single dose: 10-20 ml per 1 l water for washing, impregnated dressings and partial bathes</p>

Well-established use	Traditional use
	<p>Indication 5)</p> <p><i>Adolescents, adults and elderly</i></p> <p>Single dose: 10-20 ml per 1 l water for washing, impregnated dressings and partial bathes</p> <p>Preparation m)</p> <p>Indication 1)</p> <p><i>Adolescents, adults and elderly</i></p> <p>Single dose: 5 ml in 100 ml water</p> <p>Daily dose: up to 4 times</p> <p><i>Children from (6-12 years)</i></p> <p>Single dose: 2-3 ml in 100 ml water</p> <p>Daily dose: up to 4 times</p> <p>Indication 2)</p> <p><i>Adolescents, adults and elderly</i></p> <p>Single dose: 20 ml per 1 l hot water</p> <p>Daily dose: 1-2 times</p> <p>Indication 3)</p> <p><i>Adolescents, adults and elderly</i></p> <p>Single dose: 5 ml per 100 ml warm water</p> <p>Daily dose: 3 to several times</p> <p>Indication 4)</p> <p><i>Adolescents, adults and elderly</i></p> <p>Single dose: 45 ml per 1 l water for washings, impregnated dressings and irrigations</p> <p>Daily dose: 1-2 times</p> <p>Single dose: 30 ml per 1 l water for partial bath or hip bath</p> <p>Daily dose: 1-2 times</p> <p>Preparation n) in semi-solid dosage forms (corresponding to 8% herbal substance)</p> <p>Indication 4) and 5)</p> <p><i>Children (4 weeks - 12 years), adolescents, adults and elderly</i></p> <p>Single dose: Apply a thin layer on the affected area.</p> <p>Daily dose: 2-3 times</p> <p>Preparation o) in semi-solid dosage forms (corresponding to 5.5% herbal substance).</p>

Well-established use	Traditional use
	<p data-bbox="810 181 1054 212">Indication 4) and 5)</p> <p data-bbox="810 237 1193 268"><i>Adolescents, adults and elderly</i></p> <p data-bbox="810 277 1378 340">Single dose: Apply a thin layer on the affected area.</p> <p data-bbox="810 349 1118 380">Daily dose: several times</p> <p data-bbox="810 416 1007 448">Preparation p)</p> <p data-bbox="810 481 1054 512">Indication 4) and 5)</p> <p data-bbox="810 528 1193 560"><i>Adolescents, adults and elderly</i></p> <p data-bbox="810 566 1374 629">Single dose: 20 ml per 1 l for compresses and irrigation</p> <p data-bbox="810 638 1206 669">Daily dose: one to several times</p> <p data-bbox="810 696 1414 759">Single dose: 20-40 ml in 20-40 l water for partial bathes</p> <p data-bbox="810 768 1062 799">Daily dose: one time</p> <p data-bbox="810 826 1394 857">Single dose: 30 ml in 150 l water for full bathes</p> <p data-bbox="810 866 1062 898">Daily dose: one time</p> <p data-bbox="810 920 1174 952"><i>Children (4 weeks - 12 years)</i></p> <p data-bbox="810 958 1418 990">Single dose: 10-20 ml in 10-20 l water for bathes</p> <p data-bbox="810 999 1062 1030">Daily dose: one time</p> <p data-bbox="810 1064 1409 1202">The use in children under 12 years of age (see exceptions for children and infants) is not recommended (see section 4.4 'Special warnings and precautions for use').</p> <p data-bbox="810 1232 1019 1263">Duration of use</p> <p data-bbox="810 1288 1410 1426">If the symptoms persist more than one week during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted.</p> <p data-bbox="810 1456 1153 1487">Method of administration</p> <p data-bbox="810 1512 1070 1543">Indication 1) oral use</p> <p data-bbox="810 1568 1177 1599">Indication 2) steam inhalation</p> <p data-bbox="810 1624 1166 1655">Indication 3) oromucosal use</p> <p data-bbox="810 1680 1238 1711">Indication 4) and 5) cutaneous use</p>

4.3. Contraindications

Well-established use	Traditional use
	<p>Hypersensitivity to the active substance and to other plants of the Asteraceae (Compositae) family.</p> <p>Use as bath additive:</p> <p>Full baths are contraindicated in cases of open wounds, large skin injuries, acute skin diseases, high fever, severe infections, severe circulatory disturbances and cardiac insufficiency.</p> <p>Partial baths or hip baths are contraindicated in cases of open wounds, large skin injuries, acute skin diseases, high fever and severe infections.</p>

4.4. Special warnings and precautions for use

Well-established use	Traditional use
	<p>All methods of administration</p> <p>The use of the herbal preparations b, c, i, j, k, and o in children under 12 years of age has not been established due to lack of adequate data.</p> <p>Indication 1)</p> <p>The oral use of the herbal tea for children below 6 months of age has not been established due to general considerations of nutrition and fluid intake.</p> <p>The oral use of herbal preparations e, g, l, m in children under 6 years of age has not been established due to lack of adequate data.</p> <p>The oral use of herbal preparations b, d, h, i, j, k in children under 12 years of age has not been established due to lack of adequate data.</p> <p>Indication 2)</p> <p>The use of herbal preparations e, g, h, k, l, m as steam inhalation in children under 12 years of age has not been established due to lack of adequate data.</p> <p>Indication 3)</p> <p>The use of herbal preparation h for mouth washes or gargling in children under 6 years of age has not been established due to lack of adequate data.</p> <p>The use of herbal preparations a, c, d, e, i, j, k, l, m for mouth washes or gargling in children under 12 years of age has not been established due to</p>

Well-established use	Traditional use
	<p>lack of adequate data.</p> <p>Indication 4)</p> <p>The use of herbal preparations p or partial bathes or hip bathes in children under 4 weeks of age has not been established due to lack of adequate data.</p> <p>The use of herbal preparations a, c, d, e, g, h, i, j, k, l, m, for partial baths, hip bathes or local cutaneous use in children under 12 years of age has not been established due to lack of adequate data.</p> <p>Indication 5)</p> <p>The use of herbal preparation n for local cutaneous use in children under 4 weeks of age has not been established due to lack of adequate data.</p> <p>The use of herbal preparations f for local cutaneous use in children under 6 years of age has not been established due to lack of adequate data.</p> <p>The use of herbal preparations a, c, d, e, g, i, j, k, l, m, p (partially) for irrigations or impregnated dressings or local cutaneous use in children under 12 years of age has not been established due to lack of adequate data.</p> <p>If the symptoms worsen during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted.</p> <p>For tinctures and preparations containing ethanol, the appropriate labelling for ethanol, taken from the 'Guideline on excipients in the label and package leaflet of medicinal products for human use', must be included.</p>

4.5. Interactions with other medicinal products and other forms of interaction

Well-established use	Traditional use
	<p>For patients after renal transplantation taking high dosages for longer periods (about two months) interactions based on effects on CYP450 have been reported.</p>

4.6. Fertility, pregnancy and lactation

Well-established use	Traditional use
	<p>Preparation a) Safety during pregnancy and lactation has been established.</p> <p>Preparation b) to p) In the absence of sufficient data, the use during pregnancy and lactation is not recommended.</p> <p>If applicable before nursing the baby the nipples should be cleaned of matricaria containing products for cutaneous use to prevent a sensitization of the baby.</p> <p>No fertility data available.</p>

4.7. Effects on ability to drive and use machines

Well-established use	Traditional use
	No studies on the effect on the ability to drive and use machines have been performed.

4.8. Undesirable effects

Well-established use	Traditional use
	<p>Hypersensitivity reactions including severe allergic reaction (dyspnoea, Quincke's disease, vascular collapse, anaphylactic shock) following mucosal contact with liquid chamomile preparations have been reported. The frequency is not known.</p> <p>If other adverse reactions not mentioned above occur, a doctor or a qualified health care practitioner should be consulted.</p>

4.9. Overdose

Well-established use	Traditional use
	No case of overdose has been reported.

5. Pharmacological properties

5.1. Pharmacodynamic properties

Well-established use	Traditional use
	Not required as per Article 16c(1)(a)(iii) of Directive 2001/83/EC as amended.

5.2. Pharmacokinetic properties

Well-established use	Traditional use
	Not required as per Article 16c(1)(a)(iii) of Directive 2001/83/EC as amended.

5.3. Preclinical safety data

Well-established use	Traditional use
	Adequate tests on reproductive toxicity, genotoxicity and carcinogenicity have not been performed.

6. Pharmaceutical particulars

Well-established use	Traditional use
	Not applicable.

7. Date of compilation/last revision

1 July 2014